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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,569	07/11/2003	Robin A. Robinson	NVR-404	5752
959	7590	02/10/2006	EXAMINER	
LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			HILL, MYRON G	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 02/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/617,569	ROBINSON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Myron G. Hill	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 34-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 34-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/27/05, 11/8/05</u> . | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of claims corresponding to Group I in the reply filed on 8 November 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Furthermore, there are no pending claims to additional groups, thus the traverse is moot.

Claims 34-55 are under consideration.

### ***Priority***

There is no claim for priority noted.

### ***Information Disclosure Statement***

Signed and initialed copies of the IDS papers filed 4/27/2005 and 11/8/2005 are enclosed.

### ***Claim Objections***

Claim 44 contains the trademark/trade name Novasomes®. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The

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claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe non-phospholipid liposomes and, accordingly, the identification/description is indefinite.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 52 and 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are drawn to levels of activity and recite a specific level but there is no comparative basis or defined amount of initial substrate. The metes and bounds of the limitations cannot be determined without a relative comparative basis.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 48 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was

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not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim recites 60 to 80nm.

Applicant points to Examples 1 and 11 for support of the added claim.

The Examples disclose only that two particle sizes are seen.

The examiner only sees support for approximately 80 nm and not a range.

Applicant is requested to point to support if it exists elsewhere in the specification.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 34-42, and 45-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Latham *et al.* (J of Virology Vol 75, pages 6154-6165, from IDS) and Saito *et al.* (Vaccine 2001 Vol. 20 pages 125-133).

The claims are drawn to an avian influenza virus like particle (vlp) comprising the HA, NA and M1 proteins wherein the vlp exhibits HA or NA activity.

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Latham *et al.* teach virus like particles comprising the HA, NA, M1, and M2 influenza proteins (page 6160, column 1, start of last paragraph). These particles are about 80 nm (Figure 6) and they contain peplomers (page 6160, column 2, start of last paragraph). These VLPs are safe for working with pandemic strain viruses because they do not release genes the population does not have recent exposure to (page 6164, column 1, last full paragraph).

Latham *et al.* do not teach avian influenza VLPs.

Saito *et al.* teach H9N2 (avian and human isolated, abstract and section 2.1).

One of ordinary skill in the art at the time of invention would have been motivated to make H9N2 VLPs knowing that for influenza pandemic preparedness one of ordinary skill in the art would study new isolates (Saito *et al.* page 125, column 2, start of last paragraph). In vitro expressed HA and NA are well known in the art to have enzymatic activity. The particles made by Latham *et al.* have the expected structure and immunoreactivity and it would be expected that other VLPs would be similar and would also possess enzymatic activity.

Thus, it would be *prima facie* obvious to make the VLPs of Latham *et al.* with the H9N2 viruses of Saito *et al.* to make the claimed avian influenza VLPs with the expectation of success knowing that VLPs can be made with just 4 influenza proteins as taught by Latham *et al.*

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Claims 34, and 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Latham *et al.* (J of Virology Vol 75, pages 6154-6165, from IDS) and Gupta *et al.* (Vaccine 2001 Vol. 14 pages 219-225).

The claims are drawn to an avian influenza virus like particle (vlp) comprising the HA, NA and M1 proteins wherein the vlp exhibits HA or NA activity and further comprise and adjuvant.

Latham *et al.* is discussed above.

Latham *et al.* do not teach adjuvants.

Gupta *et al.* teach Novasomes are good adjuvants for protein immunogens and induce antibodies as well as reference adjuvants and also stimulate a TH1 like response which is involved in cell mediated immunity (Discussion pages 223-224).

One of ordinary skill in the art at the time of invention would have been motivated to use adjuvants with the VLPs because they are not living and adjuvants are known to increase the immune response to protein antigens.

Thus, it would be *prima facie* obvious to make the VLPs of Latham *et al.* with the adjuvants of Gupta *et al.* to make the claimed composition with the expectation of success knowing that Novasomes increase the immune response to protein antigens.

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**Conclusion**

No claim is allowed.

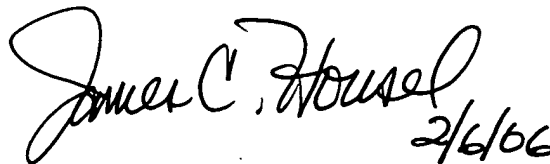
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Myron G. Hill  
Patent Examiner  
2/2/2006



JAMES HOUSEL  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600